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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NATNITHITHADHA, NAVIN	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 03/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/669,397	SOHRAB, BORZU	
	Examiner	Art Unit	
	Navin Natnithithadha	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *40,42-51 and 58-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *42-51* is/are allowed.

6)☒ Claim(s) *40 and 58-66* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claims 1-12, 14-39, 41, and 52-57 have been cancelled. Claims 40, 42, 43, and 45-47 have been amended. Claims 58-66 have been added. Claims 40 and 42-51 are pending.

2. The objections to claims 43 and 45-47 are WITHDRAWN in view of the Amendment.

Response to Arguments

3. Applicant's arguments filed 03 January 2006 have been fully considered but they are not persuasive.

Claim 40: Applicant contends that "the tube 52a is wrapped about the outer surface of the axial core 52b, and there is no suggestion in Uchigaki et al that the outer and inner electrodes are spaced from each other in a co-axial relationship. In addition, there is no teaching or suggestion in Uchigaki et al that its device could include a micro-needle that is formed by an outer electrode of its electrochemical cell, as in the present claim 40." However, Applicant's interpretation of Uchigaki is incorrect. Tube 52a can be interpreted by Uchigaki to be both or comprises of both an "outer electrode" and a "micro-needle formed at least partially by the outer electrode." Uchigaki states "tube 52a of the lancet 52, a... hollow needle" (see fig. 9 and col. 13, lines 35-40). In addition, "the tube [electrode] 52a and the axial core [electrode] 52b, respectively, are separated

through the insulation layer 52c" (see col. 13, lines 9-10). This separation or spacing is illustrated by the dark portion 52c in Figure 9 of Uchigaki (notice electrode 52b is connected to contact 53b). Thus, since Uchigaki anticipates Applicant's claimed invention, the rejection of claim 40 is MAINTAINED.

Claims 58 and 59: Applicant contends that Uchigaki's "recognition of a puncturing depth that is 'smaller than the conventional apparatus' or 'smaller depth than is necessary', does not suggest" the specific depths claimed as "no greater than the viable epidermis" and "no greater than the stratum corneum". However, because Uchigaki's teaching is broader and, thus, encompasses the claimed subject matter, Uchigaki anticipates Applicant's claimed invention. Thus, since Uchigaki anticipates Applicant's claimed invention, the rejection of claims 58 and 59 is MAINTAINED.

Claim 60: Applicant contends that "Uchigaki et al do not suggest that its hydrophilic polymer layer absorb a target constituent at an open end of a micro-needle". However, the hydrophilic high polymer layer is a reactive layer for reacting an enzyme to glucose when the reactive layer is dissolved in blood (see col. 3, lines 52-55). Thus, since Uchigaki anticipates Applicant's claimed invention, the rejection of claim 60 is MAINTAINED.

Claims 61-66: Applicant did not make any argument for patentability of the subject matter specified in claims 61-66 (Applicant's argument is based on the electrochemical cell structure in claim 40). Thus, the rejections for these claims are MAINTAINED.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 40, 58-64, and 66 are rejected under 35 U.S.C. 102(e) as being anticipated by Uchigaki et al, US 6,830,551 B1.

Claim 40: Uchigaki teaches a method for "determining the concentration of at least one target constituent contained within biological fluid" (method of using a body fluid measuring apparatus for measuring the concentration of a specific component contained in body fluid such as glucose concentration in blood) (see col. 1, lines 6-10 and fig. 9), the method comprising the steps of:

providing "at least one micro-needle" (lancet) 52 comprising an "open distal end" (not labeled, see location of 52d) and a "lumen" (space) 52d;

providing an "electrochemical cell" 52 within the lumen (the lancet is also the electrochemical cell), the electrochemical cell comprising an outer electrode (tube) 52a and an inner electrode (axial core 52b), wherein the electrodes each have a cyclindrical configuration and are spaced from each other in co-axial relationship, the micro-needle formed at least partially by the outer electrode (tube 52a acts as an active electrode and the tube 52a, which concentrically layered around and spaced apart from the axial core 52b, acts as a counterpart electrode) (see fig. 9 and col. 13, lines 23-30);

"inserting the open distal end of the micro-needle into the skin to a selected depth" (injures the skin with the lancet tip at the depth shown in fig. 9) (see col. 3, lines 31-36); and

"transferring a sample of at least one target constituent within the biological fluid present at the open distal end through the lumen and into the electrochemical cell" (blood along with glucose molecules is sucked into the fluid-sucking chamber by a capillary phenomenon) (see col. 3, lines 40-43).

In regards to limitations "providing a first electrical signal to the electrochemical cell; and receiving a second electrical signal generated by the electrochemical cell, wherein the second electrical signal is representative of the concentration the constituent in the biological fluid," the Applicant states in paragraph [0066] of the Specification the following:

> In the sensor systems of the present invention, the reference and working electrodes of the electrochemical cell are in electrical communication with a control means that sets the input reference signal transmitted to the electrochemical cell, receives the output signal from the electrochemical cell and then derives the concentration level of the analyte within the sample from the output signal. In other words the control means provides a means for applying an electrical current between the two electrodes, measuring a change in the current over time and relating the observed change in current to the concentration of analyte present in the electrochemical cell. The concentration of the analyte in the patient's blood is then derived, the numerical value of which is preferably provided as an output signal to a display means.

Uchigaki teaches applying a predetermined voltage to electrode 52a ("first electrical signal") to cause an anodal current in which the electronic circuit 24 measures the concentration of glucose in the blood sample on the basis of the current generated at electrode 52b ("second electrical signal") (see col. 10, line 66, to col. 11, line 7, and col. 13, lines 23-30). Thus, Uchigaki teaches the last two limitations in the claim based on the Applicant's disclosure. Therefore, Uchigaki anticipates claim 40.

Claims 58 and 59: Uchigaki teaches the selected depth for puncturing the skin with lancet 52 may be "smaller than the conventional apparatus" (see col. 14, lines 16-19) or "pierce the skin to a smaller depth than is necessary" (see col. 5, lines 39-42). This depth would clearly be no greater than the "viable epidermis" or "stratum corneum."

Claim 60: Uchigaki teaches a "hydrophilic gel material" (a reactive layer containing a hydrophilic high polymer) 37/57 in contact with the electrochemical cell 52 and absorbs the biological fluid including glucose molecules (see col. 8, lines 2-19, col. 11, line 65 to col. 12, line 6, and fig. 9).

Claims 61 and 62: Uchigaki teaches a "control unit" (electronic circuit) in "electrical communication" with the electrochemical cell 52 and "deriving the concentration of the constituent in the patient's biological fluid from the second electrical signal" (calculates the value measured for the test material included in the blood glucose level on the basis of the current generated at the electrode) (see col. 13, lines 26-30).

Claim 63: Uchigaki teaches a display 22 for "displaying the concentration of the constituent in the patient's biological fluid from the second electrical signal" (the result of measurement is displayed) (see col. 11, lines 1-7).

Claim 64: Uchigaki teaches the electronic circuit 24 comprises a microcomputer and other components (see col. 10, lines 5-6), which would clearly include "software algorithm" to determine a measuring value such as the blood glucose level of the matter to be detected from the anode current (see col. 10, lines 6-8).

Claim 66: Uchigaki teaches the claimed limitation as maintaining the bodily fluid in the reactive layer 37 for 15 seconds and then applying the voltammetry for

measurement (see col. 12, lines 8-21). This amount of time (15 seconds) is less the amount of time (between 30 seconds to 5 minutes) needed to equilibrate a hydrophilic polymer layer as known in the art (see Kwon, US 6,207,400 B1, col. 6, lines 50-56). Thus, Uchigaki anticipates claim 51.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable by Uchigaki et al, US 6,830,551 B1, as applied to claim 45 above, and further in view of Kwon et al, US 6,207,400 B1.

Claim 65: As to claim 50, Uchigaki teaches the following (see col. 12, lines 8-21):

> As the method for measurement, the state, in which the NaCl aqueous solution is sucked in the space 39, is maintained for 15 seconds and then cyclic voltammetry is applied. As conditions for measurement, a sweep rate was 100 mV/sec and a sweep range was 0 to 1000 mV. The results of the measurement will be shown in FIG. 7.

It is not clear as to whether Uchigaki discloses the step of maintaining the NaCl aqueous solution, which represents a body fluid sample, for 15 seconds in order to equilibrate the reactive layer 37. However, Kwon teaches the following (see col. 6, lines 50-56):

> The gel may be applied to the target surface and sufficient time allowed for analyte form the target surface to equilibrate in the gel prior to the detection step. The time may be quite short such as from 30 seconds to 5 minutes. Detection may then be carried out by applying the sensing means to the gel such as by contacting a membrane containing a suitable enzyme system for the analyte with the hydrogel.

Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Uchigaki to maintain the body fluid sample for 30 seconds to 5 minutes prior to measurement thus equilibrating the hydrophilic polymer layer 37/57 in order provide an accurate measurement.

Allowable Subject Matter

6. Claims 42-51 are allowed.

7. The following is a statement of reasons for the indication of allowable subject matter:

Claims 42-51: Zier, US 4,919,141, teaches an electrochemical cell comprising a "parallely-spaced electrode configuration" (see figs. 2 and 3). However, neither Zier nor the prior art of record teaches providing an electrochemical cell comprising a parallely-spaced electrode configuration positioned substantially transverse to the micro-needle.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (571) 272-4732. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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16 March 2006

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